DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-714/S-007

Pharmacia Consumer Healthcare
100 Route 206 North
Peapack, NJ 07977

Attention: Fred J. Frullo
Associate Director, Regulatory Affairs

Dear Mr. Frullo:

Please refer to your supplemental new drug application dated July 14, 1999, received July 16 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nicotrol inhaler (nicotine inhalation system).

We acknowledge receipt of your submission dated May 11, 2001. This submission constituted a complete response to our January 14, 2000 action letter.

This supplemental new drug application provides for revised Geriatric Use labeling.

We have completed the review of this supplemental application, as amended, and it is approved effective in the date of this letter, for use as recommended in the submitted final printed labeling (package insert submitted May 11, 2001).

The following grammatical errors should be corrected in the PRECAUTIONS section, Geriatric Use subsection, at the next printing.

1. 2nd sentence, replace 6th word "has" with "have"

2. 3rd sentence, replace 12th word "usally" with "usually"

In addition, please submit three copies of the introductory promotional materials that you propose to use for these products. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Judit Milstein, Regulatory Project Manager, at (301) 827-7440.

Sincerely,

{See appended electronic signature page}

Cynthia McCormick, M.D.
Director
Division of Anesthetic, Critical Care, and
Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research